

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use several sheets if necessary) (PTO-1449)	ATTACHMENT NO. 19603/481 (CRF D-2472A)	SERIAL NO. 09/528,014
	APPLICANT Barany et al.	
	FILING DATE March 17, 2000	GROUP ART UNIT 1655

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPRO- PRIATE
<i>M</i>	✓	1	4,683,202	07/28/1987	Mullis		
	✓	2	4,883,750	11/28/1989	Whiteley et al.		
	✓	3	4,988,617	01/29/1991	Landegren et al.		
	✓	4	5,035,996	07/30/1991	Hartley		
	✓	5	5,202,231	04/13/1993	Drmanac et al.		
	✓	6	5,314,809	05/24/1994	Erllich et al.		
	✓	7	5,352,582	10/04/1994	Lichtenwalter et al.		
	✓	8	5,324,633	06/28/1994	Fodor et al.		
	✓	9	5,424,186	06/13/1995	Fodor et al.		
	✓	10	5,143,854	09/01/1992	Pirrung et al.		
	✓	11	5,405,783	04/11/1995	Pirrung et al.		
	✓	12	5,415,839	05/16/1995	Zaun et al.		
	✓	13	5,648,213	07/15/1997	Reddy et al.		
	✓	14	5,858,659	01/12/1999	Sapolsky et al.		

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<i>M</i>	✓	15	WO 91/17239	11/14/1991	WIPO		
	✓	16	WO 96/06190	02/29/1996	WIPO		
	✓	17	WO 92/T6655 (English abstract)	10/01/1992	WIPO		
	✓	18	WO 89/10977	11/16/1989	WIPO		
	✓	19	WO 94/11530	05/26/1994	WIPO		
	✓	20	WO 93/17126	09/02/1993	WIPO		
	✓	21	WO 94/09022	04/28/1994	WIPO		

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EXAMINER <i>M</i>	22	Watson et al., "In Vitro Mutagenesis," <u>Recombinant DNA</u> , Second Edition, New York, New York: W. H. Freeman and Company, pp. 191-194 (1983)
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M	✓	23	5,242,794	09/07/1993	Whiteley et al.		
	✓	24	4,889,818	12/26/1989	Gelfand et al.		
	✓	25	4,749,647	06/07/1988	Thomas et al.		
	✓	26	5,371,241	12/06/1994	Brush		
	✓	27	5,407,798	04/18/1995	Martinelli et al.		
	✓	28	5,412,087	05/02/1995	McGall et al.		
	✓	29	5,494,810	02/27/1996	Barany et al.		
	✓	30	5,470,705	11/28/1995	Grossman et al.		
	✓	31	5,525,464	06/11/1996	Drmanac et al.		
	✓	32	5,536,649	07/16/1996	Fraiser et al.		
	✓	33	5,593,840	01/14/1997	Bhatnagar et al.		
	✓	34	5,731,171	03/24/1998	Bohlander		
	✓	35	5,744,305	04/28/1998	Fodor et al.		
	✓	36	5,800,984	09/01/1988	Vary		
	✓	37	5,834,181	11/10/1998	Shuber		

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M		38	EP 0 336 731 A2	10/11/1989	Europe		
		39	EP 0 324 616 A2	07/19/1989	Europe		
		40	EP 0 130 515 A2	09/01/1985	Europe		
		41	EP 0 246 864 A2	11/25/1987	Europe		
		42	WO 89/09835	10/19/1989	WIPO		

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EXAMINER R2	43 Takahashi et al., "Thermophilic DNA Ligase - Purification and Properties of the Enzyme from <i>Thermus Thermophilus</i> HB8," <u>J. Biol. Chem.</u> 259(16):10041-10047 (1984)	DATE CONSIDERED March '02
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<i>W</i>	✓	44	5,912,148	06/15/1999	Eggerding		
	✓	45	6,054,564	04/25/2000	Barany		
	✓	46	5,981,176	11/09/1999	Wallace		
	✓	47	5,242,794	09/07/1993	Whiteley et al.		
	✓	48	4,749,647	06/07/88	Thomas et al.		
	✓	49	5,667,974	09/16/1997	Birkenmeyer et al.		
<i>W</i>	✓	50	5,391,480	02/21/1995	Davis et al.		

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<i>W</i>	✓	51	EP 0 320 308 A2	06/14/1989	Europe		
	✓	52	WO 92/10588	06/25/1992	WIPO		
	✓	53	WO 90/15070	12/13/1990	WIPO		
	✓	54	EP 0 601 714 A1	06/15/1994	Europe		
	✓	55	WO 94/17206	08/04/1994	WIPO		
	✓	56	WO 90/11372	10/04/1990	WIPO		
	✓	57	WO 94/17210	08/04/1994	WIPO		
<i>W</i>	✓	58	WO 93/20236	10/14/1993	WIPO		

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<i>W</i>	✓	59	Saiki et al., "Enzymatic Amplification of β -Globin Genomic Sequences and Restriction Site Analysis for Diagnosis of Sickle Cell Anemia," <u>Science</u> 230:1350-1354 (1985)
<i>W</i>	✓	60	Saiki et al., "Primer-Directed Enzymatic Amplification of DNA with a Thermostable DNA Polymerase," <u>Science</u> 239:487-491 (1988)
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<i>W</i>			<i>March 82</i>
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	✓	61	Kumar et al., "Oncogene Detection at the Single Cell Level," <u>Oncogene</u> 3(6):647-651 (1988)
	✓	62	Landegren et al., "A Ligase-Mediated Gene Detection Technique," <u>Science</u> 241:1077-1080 (1988)
	✓	63	Landegren et al., "DNA Diagnostics -- Molecular Techniques and Automation," <u>Science</u> 242:229-237 (1988)
	✓	64	Iovannisci et al., "Ligation Amplification and Fluorescence Detection of Mycobacterium Tuberculosis DNA," <u>Mol. Cell. Probes</u> 7(1):35-43 (1993)
	✓	65	Wu et al., "The Ligation Amplification Reaction (LAR)-Amplification of Specific DNA Sequences Using Sequential Rounds of Template-Dependent Ligation," <u>Genomics</u> 4:560-569 (1989)
	✓	66	Darnell et al., "Manipulating Macromolecules," <u>Molecular Cell Biology</u> , Second Edition, New York, New York: W. H. Freeman and Company, pp. 189-225 (1990)
	✓	67	Eckert et al., "High Fidelity DNA Synthesis by the <i>Thermus aquaticus</i> DNA Polymerase," <u>Nucleic Acids Res.</u> 18(13):3739-3744 (1990)
	✓	68	Kwok et al., "Effects of Primer-Template Mismatches on the Polymerase Chain Reaction: Human Immunodeficiency Virus Type 1 Model Studies," <u>Nucleic Acids Res.</u> 18(4):999-1005 (1990)
	✓	69	Suzuki et al., "Detection of <i>Ras</i> Gene Mutations in Human Lung Cancers by Single-Strand Conformation Polymorphism Analysis of Polymerase Chain Reaction Products," <u>Oncogene</u> 5:1037-1043 (1990)

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	✓	70	Barany, "Genetic Disease Detection and DNA Amplification Using Cloned Thermostable Ligase," <u>Proc. Nat'l. Acad. Sci. USA</u> 88:189-193 (1991)
	✓	71	Barany, "The Ligase Chain Reaction in a PCR World," <u>PCR Methods and Applications</u> 1:5-16 (1991)
	✓	72	Eckert et al., "DNA Polymerase Fidelity and the Polymerase Chain Reaction," <u>PCR Methods and Applications</u> 1(1):17-24 (1991)
	✓	73	Erlich et al., "Recent Advances in the Polymerase Chain Reaction," <u>Science</u> 252:1643-1651 (1991)
	✓	74	Kuppuswamy et al., "Single Nucleotide Primer Extension to Detect Genetic Diseases: Experimental Application to Hemophilia B (Factor IX) and Cystic Fibrosis Genes," <u>Proc. Natl. Acad. Sci. USA</u> 88:1143-1147 (1991)
	✓	75	Mitsudomi et al., "Mutations of <i>ras</i> Genes Distinguish a Subset of Non-Small-Cell Lung Cancer Cell Lines from Small-Cell Lung Cancer Cell Lines," <u>Oncogene</u> 6:1353-1362 (1991)
	✓	76	Tada et al., "Clinical Application of <i>ras</i> Gene Mutation for Diagnosis of Pancreatic Adenocarcinoma," <u>Gastroent.</u> 100:233-238 (1991)
	✓	77	Winn-Deen et al., "Sensitive Fluorescence Method for Detecting DNA Ligation Amplification Products," <u>Clinical Chemistry</u> 37(9):1522-1523 (1991)
	✓	78	Anderson et al., "Prevalence of RAS Oncogene Mutation in Head and Neck Carcinomas," <u>The Journal of Otolaryngology</u> 21(5):321-326 (1992)
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	79	Devlin, "Textbook of Biochemistry, with clinical correlations," A Wiley Medical publication, pp. 985-995 (1982)
	80	Sandy et al., "Genotypic Analysis of Mutations in <i>Taq</i> I Restriction Recognition Sites by Restriction Fragment Length Polymorphism/Polymerase Chain Reaction," <u>Proc. Natl. Acad. Sci. USA</u> 89:890-894 (1992)
	81	Sidransky et al., "Identification of <i>ras</i> Oncogene Mutations in the Stool of Patients with Curable Colorectal Tumors," <u>Science</u> 256:102-105 (1992)
	82	Bottema et al., "PCR Amplification of Specific Alleles: Rapid Detection of Known Mutations and Polymorphisms," <u>Mutation Research</u> 288(1):93-102 (1993)
	83	Cariello et al., "Mutational Analysis Using Denaturing Gradient Gel Electrophoresis and PCR," <u>Mutation Research</u> 288:103-112 (1993)
	84	Cotton, "Current Methods of Mutation Detection," <u>Mutation Research</u> 285(1):125-144 (1993)
	85	Fan et al., "Limitations in the Use of SSCP Analysis," <u>Mutation Research</u> 288:85-92 (1993)
	86	Lu et al., "Quantitative Aspects of the Mutant Analysis by PCR and Restriction Enzyme Cleavage (MAPREC)" <u>PCR Methods and Appl.</u> 3:176-180 (1993)
	87	Pourzand et al., "Genotypic Mutation Analysis by RFLP/PCR," <u>Mutation Research</u> 288(1):113-121 (1993)
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M	✓	88	Powell et al., "Molecular Diagnosis of Familial Adenomatous Polyposis," <u>The New England Journal of Medicine</u> 329(27):1982-1987 (1993)
	✓	89	Rust et al., "Mutagenically Separated PCR (MS-PCR): A Highly Specific One Step Procedure for Easy Mutation Detection," <u>Nucl. Acids Res.</u> 21(16):3623-3629 (1993)
	✓	90	New England Biolabs Catlog, p. 63, Beverly, MA 1986 <i>no date provided</i>
	✓	91	Balles et al., "Facilitated Isolation of Rare Recombinants by Ligase Chain Reaction: Selection for Intragenic Crossover Events in the <i>Drosophila optomotor-blind</i> Gene," <u>Molec. Gen. Genet.</u> 245:734-740 (1994)
	✓	92	Barnes, "PCR Amplification of Up To 35-kb DNA With High Fidelity and High Yield From λ Bacteriophage Templates," <u>Proc. Natl. Acad. Sci. USA</u> 91(6):2216-2220 (1994)
	✓	93	Cheng et al., Effective Amplification of Long Targets From Cloned Inserts and Human Genomic DNA," <u>Proc. Natl. Acad. Sci. USA</u> 91(12):5695-5699 (1994)
	✓	94	Grossman et al., "High-Density Multiplex Detection of Nucleic Acid Sequences: Oligonucleotide Ligation Assay and Sequence-Coded Separation," <u>Nucleic Acids Research</u> 22(21):4527-4534 (1994)
M	✓	95	Hayashi et al., "Genetic Diagnosis Identifies Occult Lymph Node Metastases Undetectable by the Histopathological Method," <u>Cancer Res.</u> 54:3853-3856 (1994)
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M	96	Jen et al., "Molecular Determinants of Dysplasia in Colorectal Lesions," <u>Cancer Res.</u> 54:5523-5526 (1994)
	97	Abravaya et al., "Detection of Point Mutations With a Modified Ligase Chain Reaction (Gap-LCR)," <u>Nucleic Acids Research</u> 23(4):675-682 (1995)
	98	Berthélemy et al., "Brief Communications--Identification of K-ras Mutations in Pancreatic Juice in the Early Diagnosis of Pancreatic Cancer," <u>Annals of Internal Medicine</u> 123(3):188-191 (1995)
	99	Brennan et al., "Molecular Assessment of Histopathological Staging in Squamous-Cell Carcinoma of the Head and Neck," <u>New England Journal of Medicine</u> 332(7):429-435 (1995)
	100	Day et al., "Detection Of Steroid 21-Hydroxylase Alleles Using Gene-Specific PCR and a Multiplexed Ligation Detection Reaction," <u>Genomics</u> 29:152-162 (1995)
M	101	Frenkel, "Specific, Sensitive, and Rapid Assay for Human Immunodeficiency Virus Type 1 <i>pol</i> Mutations Associated with Resistance to Zidovudine and Didanosine," <u>Journal of Clinical Microbiology</u> 33(2):342-347 (1995)
	102	Redston et al., "Common Occurrence of APC and K-ras Gene Mutations in the Spectrum of Colitis-Associated Neoplasias," <u>Gastroenterology</u> 108:383-392 (1995)
	103	Luo et al., "Improving the Fidelity of <i>Thermus thermophilus</i> DNA Ligase," <u>Nucleic Acids Research</u> 24(14):3071-3078 (1996)
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	104	O'Dell et al., "PCR Induction of a <i>TaqI</i> Restriction Site at Any CpG Dinucleotide Using Two Mismatched Primers (CpG-PCR)," <u>Genome Research</u> 6(6):558-568 (1996)
	105	Sang et al., "Generation of Site-Directed Mutagenesis by Extralong, High-Fidelity Polymerase Chain Reaction," <u>Analytical Biochemistry</u> 233(1):142-144 (1996)
	106	Khanna et al., "Multiplex PCR/LDR for Detection of K- <i>ras</i> Mutations in Primary Colon Tumors," <u>Oncogene</u> 18:27-38 (1999)
	107	Cha et al., "Mismatch Amplification Mutation Assay (MAMA): Application to the c-H- <i>ras</i> Gene," <u>PCR Methods Appl.</u> 2(1):14-20 (1992)
	108	Haliassos et al., "Detection of Minority Point Mutations by Modified PCR Technique: A New Approach for a Sensitive Diagnosis of Tumor-Progression Markers," <u>Nucleic Acids Res.</u> 17:8093-8099 (1989)
	109	Chen et al., "A Nonradioactive, Allele-Specific Polymerase Chain Reaction for Reproducible Detection of Rare Mutations in Large Amounts of Genomic DNA: Application to Human K- <i>Ras</i> ," <u>Anal. Biochem.</u> 244:191-194 (1997)
	110	Kumar et al., "Designed Diagnostic Restriction Fragment Length Polymorphisms for the Detection of Point Mutations in <i>ras</i> Oncogenes," <u>Oncogene Res.</u> 4(3):235-241 (1989)
	111	Jacobson et al., "A Highly Sensitive Assay for Mutant <i>ras</i> Genes and its Application to the Study of Presentation and Relapse Genotypes in Acute Leukemia," <u>Oncogene</u> 9(2):553-563 (1994)
	112	Chen et al., "A Method to Detect <i>ras</i> Point Mutations in Small Subpopulations of Cells," <u>Anal. Biochem.</u> 195(1):51-56 (1991)
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m	113	DiGiuseppe et al., "Detection of K-ras Mutations in Mucinous Pancreatic Duct Hyperplasia from a Patient with a Family History of Pancreatic Carcinoma," <u>Am. J. Pathol.</u> 144(5):889-895 (1994)
	114	Kahn et al., "Rapid and Sensitive Nonradioactive Detection of Mutant K-ras Genes Via 'Enriched' PCR Amplification," <u>Oncogene</u> 6:1079-1083 (1991)
	115	Levi et al., "Multiple K-ras Codon 12 Mutations in Cholangiocarcinomas Demonstrated with a Sensitive Polymerase Chain Reaction Technique," <u>Cancer Research</u> 51(July):3497-3502 (1991)
	116	Hattori et al., "Mismatch PCR RFLP Detection of DRD2 SER311CYS Polymorphism and Schizophrenia," <u>Biochem. Biophys. Res. Commun.</u> 202(2):757-763 (1994)
	117	Hodaňová et al., "Incorrect Assignment of N370S Mutation Status by Mismatched PCR/RFLP Method in Two Gaucher Patients," <u>J. Inherit. Metab. Dis.</u> 20(4):611-612 (1997)
	118	Hoops et al., "Template Directed Incorporation of Nucleotide Mixtures Using Azole-Nucleobase Analogs," <u>Nucleic Acids Res.</u> 25(24):4866-4871 (1997)
	119	Brown et al., "Synthesis and Duplex Stability of Oligonucleotides Containing Adenine-Guanine Analogues," <u>Carbohydrate Research</u> 216:129-139 (1991)
	120	Bergstrom et al., "Design and Synthesis of Heterocyclic Carboxamides as Natural Nucleic Acid Base Mimics," <u>Nucleosides and Nucleotides</u> 15(1-3):59-68 (1996)
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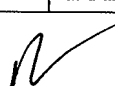
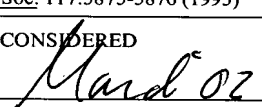
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



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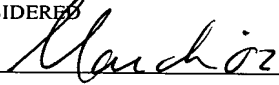
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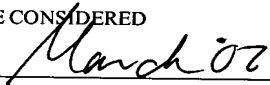
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


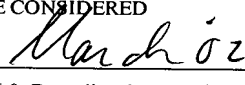
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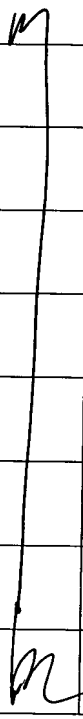

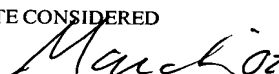
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
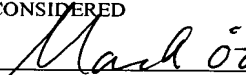
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	✓	258	5,516,635	05/14/1996	Ekins et al.		
	✓	259	5,695,934	12/09/1997	Brenner		
	✓	260	5,290,925	03/01/1994	Fino		
	✓	261	5,278,298	01/11/1994	Chakraborty et al.		
	✓	262	5,830,711	11/03/1998	Barany et al.		
	✓	263	5,258,506	11/02/1993	Urdea et al.		
	✓	264	5,859,221	01/12/1999	Cook et al.		
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	✓	278	5,506,137	04/09/1996	Mathur et al.		
	✓	279	6,033,880	03/07/2000	Haff et al.		
	✓	280	6,025,139	02/15/2000	Yager et al.		
	✓	281	6,020,124	02/01/2000	Sorenson		
	✓	282	6,013,445	01/11/2000	Albrecht et al.		
	✓	283	5,888,731	03/30/1999	Yager et al.		
	✓	284	5,869,252	02/09/1999	Bouma et al.		
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPRO- PRIATE

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANS- LATION IF APPRO- PRIATE

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)

	313	Rolfs et al., "Alternative Methods to PCR," in <u>PCR: Clinical Diagnostics and Research</u> , Berlin: Springer-Verlag, Chapter 23, pp. 263-265 (1992)
	314	Hames et al., eds., <u>Nucleic Acid Hybridisation. A Practical Approach</u> , Oxford, England: IRL Press, pp. 5-7 (1985)
	315	"Nucleic Acid Hybridization - General Aspects," in <u>Nonradioactive In Situ Hybridization Application Manual</u> , Indianapolis, Indiana: Boehringer Mannheim Corporation, Chapter III (1992)
	316	Howard et al., "Cloning the DdeI Restriction-Modification System Using a Two-Step Method," <u>Nucleic Acids Research</u> 14(20): 7939-7951 (1986)
EXAMINER		DATE CONSIDERED
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